510(k) SUMMARY

as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: April 24, 2000

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens KION Anesthesia System

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Gas machine, Anesthesia	73 BSZ	II	21 CFR 868.5160
Gas machine, Analgesia	73 ELI	II	21 CFR 868.5160
Arrhythmia Detector and Alarm	74 DSI	III	21 CFR 870.1025
Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms)	MHX	III	21 CFR 870.1025

Legally Marketed Device Identification:

Siemens KION Anesthesia System 510(k) K973971

Description of Modification:

The KION Anesthesia System original 510(k) K973971 was submitted with Siemens SC 9000 monitor [510(k) K946306] as KION's display. Two other Siemens monitors are now available for use as KION displays. Siemens SC 7000 and SC 9000XL INFINITY modular bedside monitors have received two 510(k) clearances: K982730 and K980882. When connected to a KION Anesthesia System, the SC 7000 and SC 9000XL monitors perform the same functions and have the same capabilities as a SC 9000 connected to a KION Anesthesia System. Minor hardware modifications have been made to the KION trolley to accommodate the SC 7000 and SC 9000XL monitors. As with the SC 9000, the SC 7000 and SC 9000XL monitors provide alarm annunciation for KION and allow interface to the MultiView WorkStation [510(k) K955059].

Intended Use:
The KION Anesthesia System is intended for general anesthesia use in the infant to adult populations. The KION will deliver operator set concentrations of anesthesia gases as well as deliver controlled breaths to the patient, with constant flow using a set oxygen concentration. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings.

Assessment of non-clinical performance data for equivalence: See Section J

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: See Declaration of Conformity, Section K

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 2000

Mr. David Simard
Director, QA & RA
Official Correspondent
Siemens Elema AB
Electromedical Systems Group
16 Electronics Avenue
Danvers, MA 01923

Re: K001315
Modification To Kion Anesthesia System
Regulatory Class: II (two) and III (three)
Product Code: 73 BSZ and 74 MHX
Dated: April 24, 2000
Received: April 26, 2000

Dear Mr. Simard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Brian E. Hanrahan for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001315

Device Name: KION Anesthesia System

Indications for Use:

Use of the KION Anesthesia System is indicated for the infant to adult populations in an environment where patient care is provided by Healthcare Professionals, trained in the administration of anesthesia, when the professional determines that a device is required to assist the breathing of the patient. This device can be used to administer anesthesia while controlling the entire ventilation for patients without any ability to breath, as well as supporting patients with reduced ability to breath. The KION is designed to be used in the OR or any other hospital location where administration of anesthesia is necessary. It is not intended for transport use in ambulances or helicopters in the US market.

Christy Foreman / Brun E. Adamson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001315

MRI Compatibility Statement:
Siemens KION anesthesia system is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)